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K060156

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Straight Plate with Angular Stability & Screw System

COMMON NAME: Bone Plate & Screw System

CLASSIFICATION: Plate, Fixation, Bone (see 21 CRF, Sec. 888.3030),
Screw, Fixation, Bone (see 21 CFR, Sec. 888.3040),
Washer, Bolt, Nut (see 21 CFR, Sec. 888.3030)

DEVICE PRODUCT CODE: HRS

SUBSEQUENT PRODUCT CODE: HWC, HTN

SUBSTANTIALLY EQUIVALENT DEVICES
I.T.S. GmbH Claviculaplate with Angular Stability **(K050852)**
Smith & Nephew Peri-Loc Locking Bone Plates and Locking Bone Screw System **(K051735)**
Zimmer Periarticular Locking Plates and Screws **(K051098)**
Synthes 4.5mm LCP Straight Reconstruction Plates **(K051986)**
Acumed Congruent Plate System **(K012655)**
I.T.S. GmbH FR.O.H. Calcaneus Repair System **(K051642)**
Synthes Sterile 3.5mm and 4.0mm Cannulated Screw **(K963192)**
Zimmer/Pioneer Cannulated Screw System **(K003496)**
Synthes (USA) Spherical Washers **(K052483)**

DEVICE DESCRIPTION: The I.T.S. Straight Plate with Angular Stability is a low-profile 4, 6, or 8 hole plate with various length cortical and/or cancellous self-tapping stabilization locking and/or compression screws. The Straight Plate is made from CP titanium according to ASTM F 67-00 and all screws are made from 6-4 Alloyed Titanium according to ASTM F 136-02. The plate and screws are surface conditioned with a TIODIZE, Type II preparation.

The I.T.S. Screw System is a group of cannulated fracture fixation screws in various diameters of 4.0mm, 6.5mm, and 7.3mm and lengths. A complement of flat and spherical Washers are available with the system. All screws and washers are made from 6-4 Alloyed Titanium according to ASTM F 136-02 and are surface conditioned with a TIODIZE, Type II preparation.

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INTENDED USE:

The ***intended use*** of the I.T.S. Straight Plate with Angular Stability is to stabilize an osteotomy or fracture of small bones, long bones, the pelvis and the calcaneus in an adult or pediatric patient.

Indications for use include comminuted fractures, supercondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions. And, as well, a fracture or osteotomy of the tibia, fibula, femoral condyle, acetabulum, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation. The 3.5mm Cortical and Cancellous Angle Stable Screws used in conjunction with the Straight Plate may be used only on small bones.

The ***intended use*** of the I.T.S. Screw System is for corrective osteotomy or internal fracture fixation of the patella, pelvis, ankle, and long bones in an adult or pediatric patient.

For the 4.0mm Cannulated Cancellous Screw, indications for use are for radial and ulnar fractures, fractures of the proximal/distal humerus and of the patella, and for tendon fixation, maisonneuve injuries and disruption of the syndesmosis with bimalleolar or supermalleolar fractures and the instability of the talus centering.
For the 6.5mm Cannulated Cancellous Screw, indications for use are for fractures of the femoral neck, tibiaplateau, of the sacrum and the articular cavity of the hip joint, and the metaphyseal fractures of the distal femur and distal tibia, fixation of the Ileo-sacral joint, and fusion of the foot and ank
For the 7.3mm Cannulated Cancellous Screw, indications for use are for fractures of the calcaneus, femoral neck, tibiaplateau, and of the sacrum and the articular cavity of the hip joint, fusion of the foot and ankle, fixation of the Ileo-sacral joint, and metaphyseal fractures of the distal femur and distal tibia.

The system(s) is not intended for spinal use.

BASIS OF SUBSTANTIAL EQIVLAENCE:

The I.T.S. Straight Plate with Angular Stability is substantially equivalent to the Smith & Nephew, Zimmer, Synthes, Acumed, and I.T.S. GmbH stabilizing bone plate systems. The I.T.S. Screw System is substantially equivalent to the I.T.S. GmbH, Zimmer, and Synthes cannulated screw and washer systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. Straight Plate with Angular Stability and Screw System is shown to be safe and effective for use in fracture fixation of small and long bones in the body.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2006

I.T.S. Implantat-Technologie-Systeme GmbH
c/o Engineering Consulting Services, Inc.
Mr. Albert Lippincott
Biomedical Engineer
3150 E. 200th Street
Prior Lake, Minnesota 55372

Re: K060156
Trade/Device Name: Straight Plate with Angular Stability & Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC, HTN
Dated: March 7, 2006
Received: March 8, 2006

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

I.T.S.
International Technology Systems GmbH
Tel +43 (0)676 21 21 2
Fax +43 (0)676 21 21 2
office@its-implant.com

Indications for Use

510(k) NUMBER: K060156

DEVICE NAME: **STRAIGHT PLATE WITH ANGULAR STABILITY AND SCREW SYSTEM**

The ***intended use*** of the I.T.S. Straight Plate with Angular Stability is to stabilize an osteotomy or fracture of small bones, long bones, the pelvis and the calcaneus in an adult or pediatric patient.

Indications for use include comminuted fractures, supercondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions. And, as well, a fracture or osteotomy of the tibia, fibula, femoral condyle, acetabulum, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation. The 3.5mm Cortical and Cancellous Angle Stable Screws used in conjunction with the Straight Plate may only be used on small bones.

The ***intended use*** of the I.T.S. Screw System is for corrective osteotomy or internal fracture fixation of the patella, pelvis, ankle, and long bones in an adult or pediatric patient.

For the 4.0mm Cannulated Cancellous Screw, **Indications for use** are for radial and ulnar fractures, fractures of the proximal/distal humerus and of the patella, and for tendon fixation, malsonneuve injuries and disruption of the syndesmosis with bimalleolar or supermalleolar fractures and the instability of the talus centering.
For the 6.5mm Cannulated Cancellous Screw, **Indications for use** are for fractures of the femoral neck, tibiaplateau, of the sacrum and the articular cavity of the hip joint, and the metaphyseal fractures of the distal femur and distal tibia, fixation of the lleo-sacral joint, and fusion of the foot and ankle.
For the 7.3mm Cannulated Cancellous Screw, **Indications for use** are for fractures of the calcaneus, femoral neck, tibiaplateau, and of the sacrum and the articular cavity of the hip joint, fusion of the foot and ankle, fixation of the lleo-sacral joint, and metaphyseal fractures of the distal femur and distal tibia.

The system(s) is not intended for spinal use.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K060156